



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Seventh Annual Drug Information Association/Food and Drug Administration Statistics Forum--2013; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the Drug Information Association (DIA), is announcing a public conference entitled “Seventh Annual DIA/FDA Statistics Forum--2013.” The purpose of the conference is to discuss relevant statistical issues associated with the development and review of therapeutic drugs and biologics. This meeting is intended to be an open forum for the timely discussion of topics of mutual theoretical and practical interest to statisticians and clinical investigators who are involved in the development of new drugs and biologics. A primary focus for this meeting will be to establish an ongoing dialogue regarding FDA’s “Critical Path” initiative--emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials data and measuring the progress being made in designing and implementing innovative solutions.

DATES: The public conference will be held on April 28, 2013, to May 1, 2013, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public conference will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852, 1-301-822-9200.

FOR FURTHER INFORMATION CONTACT:

Constance Burnett,
Drug Information Association,
800 Enterprise Rd.,
Horsham, PA 19044,
1-215-293-5800,
email: Constance.Burnett@diahome.org; or

Stephen Wilson,
Food and Drug Administration,
10903 New Hampshire Ave.,
Silver Spring, MD 20993,
301-796-0579,
email: Stephen.Wilson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This annual FDA/DIA statistics forum will establish a unique, open, international forum for statisticians and clinicians from industry, academia, contract research organizations, and Government Agencies. Meeting participants will learn, discuss, and collaborate on the current and emerging statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The goals of the program are to:

- Explore and implement innovative statistical solutions to issues associated with the regulatory review of therapeutic drugs and biologics.

- Describe the application of statistical methodologies and thinking to the development of new therapeutic biologics and drugs.
- Assess the impact of regulations and guidance on statistical practice.
- Discuss ideas for improving the communication between industry statisticians and FDA reviewers.

A description of the planned activities of the working groups can be found at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting>.

II. Registration and Accommodations

A. Registration

To register, please submit the registration form online at <http://www.diahome.org/en/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=30457&EventType=Meeting> (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.) Registration fees cover the cost of facilities, materials, and food functions. Seats are limited, and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference. The costs of registration for different categories of attendee are as follows:

Category	Cost
Industry Representatives	\$1,400
Charitable Nonprofit/Academic (Full time)	\$700
Government (Full time)	\$420
Tutorial Fees	\$405

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to:

Constance.Burnett@diahome.org. All registrants will pay a fee with the exception of a limited number of speakers/organizers who will have a complimentary registration.

B. Accommodations

Attendees are responsible for their own accommodations. Attendees making reservations at the Marriott Bethesda North Hotel and Conference Center, Bethesda, MD, are eligible for a reduced conference rate of \$209, not including applicable taxes. Those making reservations online should use the group code "13008" to receive the special rate. If you need special accommodations because of disability, please contact Constance.Burnett@diahome.org at least 7 days before the meeting.

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.